In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-1064V
Filed: April 30, 2008

TO BE PUBLISHED

JORDAN TAYLOR SHEPPERSON, by her mother ALISHA SHEPPERSON,	*	
Petitioner,	*	Hepatitis B vaccine; Kawasaki disease; timing of onset; autoimmune reaction within 24 hours biologically implausible; expert credibility.
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Michael G. McLaren, Memphis, Tennessee for petitioner.

Vincent J. Matanoski, United States Department of Justice, Washington, DC, for respondent.

DECISION[1]

GOLKIEWICZ, Chief Special Master.

I. PROCEDURAL BACKGROUND

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire" decision will be available to the public. Id.

On October 4, 2005, petitioner, Jordan Taylor Shepperson, by her mother Alisha Shepperson, filed a petition pursuant to the National Vaccine Injury Compensation Program[2] ("the Act" or "the Program") alleging that Jordan suffers from Kawasaki disease which was caused in fact by the DPT, Com-Vax, and IPV vaccinations she received on November 14, 2002. Petition (Pet.) at 1, 5. On January 3, 2006, respondent filed a report pursuant to Vaccine Rule 4(c) contending that "unless petitioner submits scientifically reliable proof that the IPV, DTP, and Com-Vax vaccines administered on November 14, 2002, caused Jordan's condition, this petition should be dismissed." Respondent's Report, filed January 3, 2006, at 6. Following the filing of expert reports, a Hearing was held on February 1, 2007 (hereinafter "Hearing") to elicit their testimony. Petitioner presented Vera S. Byers, M.D., Ph.D., as an expert witness. Respondent presented Jerome O. Klein, M.D., as an expert witness. After conducting closing arguments, the case is ripe for resolution. As discussed below, the undersigned finds that petitioner failed to prove her case.

II. FACTUAL BACKGROUND

With one major exception that will be discussed later, the factual background in this case is undisputed. Jordan Shepperson was born on September 6, 2002. Pet. at 1. The pregnancy was normal and labor and delivery was uneventful. Id. Jordan received her first hepatitis B (hereinafter HepB) vaccine at two days of age. Id.; P Ex. 3 at 7. During her first two months of life, Jordan developed normally. On November 14, 2002, Jordan received her first set of immunizations, which included DPT, Com-Vax (a combination of HepB and Hib vaccines, see R Ex. A at 1), and IPV, during a "well child" check-up. P Ex. 4 at 2. According to petitioner's mother, Alisha Shepperson, later that day following Jordan's immunizations, the family drove from their Kentucky home to Florida to visit her parents. P Ex. 1 (affidavit of Alisha Shepperson). According to the mother, Jordan developed a low grade (approx. 101 degrees) fever within two hours after receiving the vaccinations and became lethargic. P Ex. 1. "Hours later" Jordan developed a red rash on her forehead which gradually spread to her abdomen, genitals, buttocks, upper arms, and upper thighs. Id. Further, the mother's affidavit states that within twenty-four (24) hours, Jordan experienced vomiting and diarrhea and became fussy. Id. As will be discussed later, the medical records differ on the timing of the fever and rash.

Two days later, on November 16, 2002, Jordan's mother took her to the Fort Walton Beach Medical Center where Jordan presented with a 102 degree fever, earache, cough, runny nose, fussiness, skin rashes, and decreased activity and appetite. P Ex. 5 at 2; see also P Ex. 1.

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[2]The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act"). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

The clinical impression of the attending physician was a probable reaction to her immunizations. Id. at 3. Petitioner was instructed to give Jordan tylenol for her fever and to follow-up with her primary care physician in 1-3 days. Id. at 5; see also P Ex. 1.

According to the mother, she followed the instructions, but Jordan's rash continued to spread, her urine output decreased, and her vomiting and diarrhea increased. P Ex. 1 at 2. Jordan developed congestion and her lethargy and fever increased. Id. The mother's concerns led to her return to Kentucky where on November 19, 2002, Jordan was taken to Ephraim McDowell Regional Medical Center in Danville. Id.; see also P Ex. 6. The records give a history that since the immunization on November 14, the mother notes frequent vomiting, a loss of appetite and a fever. P Ex. 6 at 2. The record also notes that the rash was spreading over the entire body the "last 3 days" and that it first appeared after the Ibuprofen. Id. Petitioner was told to stop the Ibuprofen and to follow up with Jordan's family doctor. Id. at 5.

Jordan's mother brought her to Dr. Miller, the family physician, the next day, November 20, 2002. P. Ex. 7; see also P Ex. 1 and 7. The office visit notes reflect that Jordan "broke out in rash on Friday. Had shots Thursday." P Ex. 7. Jordan was diagnosed with urticaria and hives secondary to her immunizations. Id. She was sent to Fort Logan Hospital for observation. Id.; P Ex. 8.

The Discharge Summary from Fort Logan Hospital notes that Jordan had a temperature of 102.7 degrees. P Ex. 8 at 1. The history notes that following her immunizations "[w]ithin 24 hours the child developed a bright red rash of the face which subsequently spread to the body. [She] was seen in the ER in Florida with the family on vacation the next day and was diagnosed with allergic reaction to the shot." Id. Jordan was diagnosed with an allergic reaction to her immunizations and transferred the same day over concerns of sepsis to the University of Kentucky Children's Hospital. Id. At the University of Kentucky Hospital Jordan was examined by a dermatologist who noted that the rash appeared to have "started within 24-30 hrs of vaccination and about 12-18 hrs [after] fever began." P Ex. 9 at 24. The dermatologist also noted that Jordan's symptoms were "possibly due to immunizations, but doubtful." Id. Jordan's condition stabilized, though the condition remained serious. Id. at 2. A preliminary diagnosis of atypical Kawasaki[3] disease was made on November 26, 2002. Id. at 4. On December 2, 2002, Jordan was discharged from the hospital, under instructions to take aspirin and continue on the platelet inhibitor dipyrimadole. Id. at 5.

Jordan returned to the University of Kentucky Hospital on December 5, 2002, due to experiencing fever and green mucus in her vomit. P Ex. 10 at 1. On December 7, 2002, she was discharged with a diagnosis of Kawasaki disease and gastritis. Id. at 3.

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[3] Kawasaki disease is a "systemic vasculitis of unknown origin that occurs primarily in children under 8 years of age. Symptoms include a fever lasting more than 5 days, polymorphic rash, erythematous, dry, cracking lips, conjunctival injection, swelling of the hands and feet, irritability, adenopathy, and a perineal desquamative rash." Stedman's Medical Dictionary (27th ed. 2000) 516.

Jordan was seen on a regular basis between December 2002 and April 2005 by her physician Dr. Miller and also by her cardiologist Dr. Valerie Schroeder. See P Ex. 11-13, 15-23. Many of these visits have been routine follow-up visits. Id. The most recently provided medical record dated April 12, 2005, notes that Jordan was asymptomatic and that no significant aneurysm appeared to remain. P Ex. 23 at 5-6. Her coronary artery sizes still measured "top normal to slightly increased." Id. at 5. Jordan was still on aspirin therapy during this visit, though Dr. Schroeder recommended discontinuing aspirin therapy in her April 12, 2005, consult letter to Dr. Miller.

One factual issue in dispute and critical to the resolution of this case is the timing of Jordan's fever and subsequent rash following immunization. The experts' opinions to a great extent hinge on these facts. The Petition, relying upon the mother's affidavit, states that the onset of the fever was "within two hours" following the immunizations, and "[h]ours later" Jordan developed the rash. Pet. at 2; see also P Ex. 1 at 1-2. The contemporaneous medical records corroborate petitioner's version of the facts, except for the timing of the fever and rash. The notes from the University of Kentucky provide the varying accounts. The history recorded on admission states that 12 hours after immunizations Jordan had a high fever followed by the rash. P Ex. 9 at 13, 21. The progress notes state that "Approx. 8-10 hrs" after the shot she developed a fever and then "12-14 hrs later" she developed the rash. Id. at 22. A later "impression" notes that "Rash seems to be evolving per parent history." Id. at 24. The rash started "24-30 hrs of vaccinations and about 12-18 hrs" after the fever began. Id. On 11/22, the history notes that the rash, associated with fever, began less than 24 hours post immunization. Id. at 26. Additionally, on November 20, 2002, the discharge summary from Fort Logan Hospital stated "within 24 hours [of vaccination] the child developed a bright red rash on the face, which subsequently spread to the body." P Ex. 8 at 1.

Ultimately, it is unnecessary to resolve exactly the timing of onset of Jordan's fever and rash. What is critical, and both petitioner's version of the events and the contemporaneous medical records agree, is that the onset of Jordan's fever and rash began within 24 hours following her immunizations. Compare P Ex. 1 at 2 with P Ex. 9 at 13, 21, 22, 24, and 26; see also Transcript of February 1, 2007 Hearing (hereinafter "Tr. at __") at 59. It is this 24-hour period, not the exact timing within the 24-hour period, that is critical to the experts' discussion of the medical theory of this case.

III. DISCUSSION

A. Summary of Experts' Positions

The following is a brief overview of the experts' and their positions.

Vera S. Byers, M.D.

Dr. Byers is board-certified in internal medicine and completed a fellowship in immunology. P Ex. 26 at 5. Dr. Byers also possesses a Master's in biochemistry and immunology and a Ph.D. in basic immunology. Id. During her testimony, Dr. Byers defined clinical immunology to encompass the study of the effect of the immune system of humans and to include rheumatologic conditions, immunodeficiency disorders and the practice of allergy. Tr. at 11. Since 1998, Dr. Byers no longer sees patients, except for litigation purposes. Id. at 54. In fact, 50% of her time is spent with litigation. Id. at 17. In her clinical experience, Dr. Byers recalled seeing "maybe" three patients with the diagnosis of Kawasaki disease. Tr. at 55. However, Dr. Byers stated that she also saw children with vasculitis during her clinical immunology residency, which was before it was called Kawasaki disease. Id. Dr. Byers testified that Kawasaki disease is a vasculitis. Tr. at 36, 45. Dr. Byers has not treated any children with the diagnosis of Kawasaki disease and she is not an expert in treating the disease. Tr. at 56.

In her report, Dr. Byers noted that Jordan developed Kawasaki disease within 24 hours after her immunizations. P Ex. 25. The initial presentation was the rash. Id. at 3. Dr. Byers fingers the HepB vaccine as the likely culprit. Id.; see also Tr. at 21. Dr. Byers reasons that the HepB virus has been closely associated with Kawasaki disease. Id. at 2-3. She states that the development of the rash within a day of vaccination "is consistent with an antibody mediated mechanism of action, and since the child had previously been vaccinated only with Hepatitis B, this is the likely culprit." Id. at 3. Dr. Byers referenced a case report of a 35 day old infant developing Kawasaki disease within one day following a second dose of HepB vaccine for support of her opinion. In summary, Dr. Byers stated

> Since the child had no evidence of any other illness prior to vaccination, and no contact with sick individuals, and no evidence of infection with any of the known causes of Kawasaki's disease including EBV virus, it is, more likely than not to a reasonable degree of medical probability that the Hepatitis B vaccination caused or significantly contributed to the illness.

P Ex. 25 at 3. Dr. Byers testified, with one very critical exception, consistently with this report. The critical exception was the first symptom of manifestation of the Kawasaki disease: in her report Dr. Byers stated that the first symptom was the rash; in her testimony she stated that the first symptom was the fever. This discrepancy is a critical indicator of both Dr. Byers' knowledge of Kawasaki disease and to the important issue of timing of onset presented in this case.

Jerome O. Klein, M.D.

Dr. Klein is board-certified in pediatrics and completed a research fellowship in infectious disease. R Ex. B at 1; Tr. at 109. He is the director of Pediatric Infectious Diseases at Boston City Hospital and also a consultant in pediatrics at Massachusetts Hospital School. R Ex. B at 1. He has personally consulted on about a dozen patients with Kawasaki disease. Tr. at 114. He also has seen or discussed additional cases of Kawasaki disease with his pediatric infectious disease medical group. Id.

Dr. Klein opined that after reviewing the medical records of Jordan Shepperson and the Supplemental Report by Dr. Byers:

> [T]hat it is unlikely that the child developed KD as a result of the hepatitis B vaccinations because:
>
> 1. Investigators in many countries have sought, without success, to identify an etiology of Kawasaki disease. Although some infectious or non-infectious materials have been associated with Kawasaki disease, none have met the level of proof to indicate a reasonable degree of medical certainty.
>
> 2. Millions of infants in the US have received the hepatitis B vaccine without Kawasaki disease identified as an adverse event.
>
> 3. The temporal relationship between the vaccination and the onset of Kawasaki disease is not biologically plausible.

R Ex. D. The temporal relationship in this case, particularly the mother's contention that the fever began within two hours following immunization, was critically important to Dr. Klein's opinion. See Tr. at 117. That fact alone made it biologically implausible that the vaccine caused Jordan's Kawasaki disease. Id. at 168.

B. Legal Standard

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.[4]

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). Petitioner does not allege a table injury. See Pet. at 1 (Vaccines "caused-in-fact" petitioner's injuries); see

[4] A preponderance of the evidence standard requires a trier of fact to "believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

also P Ex. 35 at 1 (Jordan did not suffer the table injury anaphylaxis). Thus, petitioner must prove that the vaccine in-fact caused Jordan Shepperson's injury, a so-called "off-Table" case.

To demonstrate entitlement to compensation in an off-Table case, petitioners must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused or significantly aggravated the injury alleged. See, e.g., Bunting v. Sec'y of Dept. of Health & Human Servs., 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Sec'y of Dept. of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Sec'y of Dept. of Health & Human Servs., 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992); see also §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, "[petitioners must] show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Sec'y of Dept. of Health & Human Servs., 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Sec'y of Dept. of Health & Human Servs., 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Sec'y of Dept. of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Sec'y of Dept. of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by "[a] reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960.[5]

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[5] The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that "Daubert is useful in providing a framework for evaluating the reliability of scientific evidence." Terran v. Sec'y of Dept. of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert's opinion. Id. In other words, the "testimony must be supported by appropriate validation – i.e., 'good grounds,' based on what is known." Id. Factors relevant to that determination may include, but are not limited to:

> Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication "does *not* necessarily correlate with reliability," because "in some instances well-grounded but innovative theories

See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

While petitioners need not show that the vaccine was the sole or even predominant cause of the injury, petitioners bear the burden of establishing "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Nor do petitioners satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating "inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation")); Hodges, 9 F.3d at 960. Finally, petitioners do not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

In Althen v. Sec'y of Dept. of Health & Human Servs., 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioners' burden is to produce "preponderant evidence" demonstrating: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury." The Federal Circuit stated further that "requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court's well established precedent." Id. at 1281. The Federal Circuit concluded that to support petitioners theory of causation, there is no requirement in the Vaccine Act's preponderant evidence standard that petitioners submit "objective confirmation," such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature "prevents

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will not have been published." Daubert, 509 U.S. at 594. However, the Supreme Court's only guidance to lower courts in determining the reliability of a novel proposition is that

> . . . submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Althen, 418 F.3d at 1280 ("The purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."); see also, Gall v. Sec'y of Dept. of Health & Human Servs., No. 91-1642V, 1999 WL 1179611, at *8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants." Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)); see also Capizzano v. Sec'y of Dept. of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) [hereinafter "Capizzano III"]. Moreover, the Federal Circuit stated, "The purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id.

The Federal Circuit affirmed Althen's three-part test in Capizzano III and in Pafford v. Sec'y of Dept. of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006). The panel in Pafford, however, explained that the three prongs in Althen "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." Pafford, 451 F.3d at 1355. Fairly interpreted, the Pafford court held that it is petitioner's burden to rule out other competing possible causes of the injury in establishing that the vaccine was the "but-for cause of the harm." Id. at 1355, 1357; see also Althen at 1281. ("[T]he elimination of other causes [] is merely a recitation of this court's well-established precedent."). But see, Walther v. Sec'y of Dept. of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007) ("[W]e conclude that the Vaccine Act does not require petitioner to bear the burden of eliminating alternative causes when the other evidence on causation is sufficient to establish a prima facie case.").

However, the legal requirement that a petitioner support her proposed causation theory with a "sound and reliable medical or scientific explanation" is undisturbed. Knudsen, 35 F. 3d 543, 548 (Fed. Cir. 1994); see also Grant, 956 F.2d at 1148 ("A reputable or scientific explanation must support this logical sequence of cause and effect."). Thus, when considering the evidence in a case, the special master is to "consider all relevant and reliable evidence, governed by the principles of fundamental fairness to both parties." Vaccine Rule 8(c); see also DeBazan v. Sec'y of Dept. of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2000) ("A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness's testimony regarding causation"); Campbell v. Sec'y of Dept. of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006). (Althen's requirement of a "reputable medical or scientific explanation" "[l]ogically [ ] requires a special master to rely on reliable medical or scientific evidence . . . ."); Manville v. Sec'y of Dept. of Health & Human Servs., 63 Fed. Cl. 482, 491 (2004) ("Daubert adequately serves the gatekeeping function for analysis of the admissibility of evidence; once evidence has passed that test, the trier of fact's process, simply, is to determine the probativeness of that evidence."). Jordan Shepperson's case is measured against these standards.

C. Analysis

Petitioner has not alleged a table injury in this case. Pet. at 1 (alleges "caused-in-fact"). Both expert witnesses, Dr. Byers and Dr. Klein, agreed that Jordan was correctly diagnosed with Kawasaki disease (hereinafter KD), and that she did not have anaphylaxis, a "vaccine table injury

event". R. Ex. D; P Ex 35. Thus, the issue to be resolved is whether petitioner has demonstrated by the preponderance of the evidence that the DPT, Com-Vax, and IPV[6] vaccinations Jordan received on November 14, 2002, more likely than not caused her KD. For the following reasons the undersigned finds petitioner was unable to prove by a preponderance of the evidence that her immunizations were the cause in-fact of her KD.

The undersigned's analysis focuses on two primary areas: first, in agreement with Dr. Klein, it is found that the onset of Jordan's KD in less than 24 hours following immunization is biologically implausible and thus fails the Federal Circuit's test of a reliable medical theory and medically acceptable temporal relationship, Althen at 1281; and second, in accordance with the Federal Circuit's decision in Capizzano III, it is found that there is not a logical sequence of cause and effect because the totality of information regarding KD supports a finding that the vaccine's role was merely coincidental. Lastly, overarching these findings is the determination that Dr. Klein was the far more persuasive expert witness. He has far superior knowledge and experience with this admittedly rare disorder and his testimony was seen as vastly more reliable. Dr. Byers on the other hand has a number of defects as an expert and the undersigned's confidence in her testimony is lacking for a number of reasons that will be developed later.

Before discussing the evidence, some definitions of medical words appearing in this decision will be helpful. First, Kawasaki disease is defined as "an acute systemic vasculitis with predilection for coronary arteries and potential for aneurysm formation," which occurs predominately in children. P Ex. 29 at 1; R Ex. C at 1. Serious complications include "cornonary arteries, coronary artery aneurysms, and aneurysmal thrombosis or rupture." Id. Distinctive symptoms include fever, rash and irritability. Tr. at 115; R Ex. C at 1. Second, vasculitis is an inflammation of the blood vessels. Tr. at 23. Third, polyarteritis nodosa (PAN) is an inflammatory disease of small and medium muscular arteries. P Ex. 33. Infantile polyarteritis nodosa (IPAN) is PAN in infants. Id.; Tr. at 22.

Dr. Byers' opinion that Jordan's HepB vaccine caused her KD is premised upon the "interchangeable" use of the terms KD, vasculitis, PAN and IPAN. Tr. at 36. This is important to Dr. Byers' opinion because the etiology of KD is unknown, so the support for her opinion must come from other disease processes - the "interchangeable" PAN and IPAN. The essence of Dr. Byers' medical theory is that KD is an autoimmune disorder that is "triggered" by an inflammation caused by infection or, "in the case of a vaccine, it can also be a vaccine-mediated injury." Tr. at 28.

Dr. Byers lays out three reasons for attributing Jordan's KD to HepB vaccine. The first she states is a history of hepatitis B virus and HepB vaccine causing vasculitis. Tr. at 34. The second is that Jordan received a HepB vaccine before and therefore, "would be expected to have antibodies that could form antigen-antibody complexes and result in vasculitis." Id. Thirdly, Dr.

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[6] Although petitioner's claim is based upon all of the vaccines received, Dr. Byers testified solely regarding the HepB vaccine as the cause. See Tr. at 21.

Byers states that though a recombinant vaccine, "some groups" have found hepatitis B vaccine to "serve as a superantigen". Id.

Dr. Byers stated in her report that:

> The most likely mechanism of action was an initial antigen-antibody complex formation consisting of the antigen-Hepatitis B Virus in the vaccine, with anti-hepatitis B antibody. This resulted in a rash, which was the initial presentation. Although a rash can be caused by both T cells and the antibodies, the fact that it appeared within a day of vaccination is consistent with an antibody mediated mechanism of action, and since the child had previously been vaccinated only with Hepatitis B, this is the likely culprit.

Pet. Ex. 25 at 3.

Dr. Byers' medical theory is premised upon Jordan developing KD "about 24 hours after the immunizations", **with an initial presentation of a rash**.[7] P Ex. 25 at 2-3 (emphasis added). Putting all other disagreements between the experts aside, and there were many[8], this issue of Jordan developing KD within 24 hours is determinative of this case. Dr. Klein convincingly testified that it is biologically implausible that the body's immune system could react within that 24 hour period of time, thus eliminating the vaccine as a causative agent. Dr. Byers presented no

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[7] This contention by Dr. Byers calls into question her understanding of the facts of the case and the pathogenesis of KD. Clearly, the rash was not the first symptom of Jordan's KD. The medical literature submitted by both parties make clear that fever is the first symptom of KD, followed by a rash. See P Ex. 29 at 623; R Ex. F at 1; see also Tr. at 140. In addition, the mother's affidavit indicates that a low-grade fever presented two-hours after vaccination. P Ex. 1. Additionally, the contemporaneous medical records from a dermatologist at University of Kentucky Hospital noted that the rash appeared to have "started within 24-30 hrs of vaccination and about 12-18 hrs [after] fever began." P Ex. 9 at 24. The documentation of the onset of fever prior to the onset of rash conflicts with Dr. Byers' proposal that the first onset of KD was the rash, the timing of which Dr. Byers relied on for her theory for biologic plausibility. Strangely, Dr. Byers herself later testified at the Hearing to the fever as the initial symptom. See Tr. at 59, 98.

[8] The case presented numerous other areas of dispute that are unnecessary to resolve in deciding this case. For example, Dr. Byers' working premise is that KD is a vasculitis more "generally known as polyarteritis nodosa, except it's polyarteritis in children." Tr. at 22. Dr. Byers stated that the medical terms KD, vasculitis, PAN and IPAN are "interchangeable." Id. at 36. Dr. Klein disagreed completely. See Tr. at 120-21. In addition, the experts disagreed whether the medical experience with hepatitis B virus can be extrapolated to the HepB vaccine. Compare Tr. at 37-8 with Tr. at 124-25. The literature submitted provides some support for each expert's position, but does not answer, at least in the undersigned's mind, these very important medical issues. Prudence dictates that the undersigned not attempt to address and resolve these disputes without further explication, especially since resolution is unnecessary in light of how this case is decided. Accordingly, an in-depth discussion of the literature submitted by the parties is unnecessary.

persuasive explanation for the short time period, and presented no effective rebuttal to Dr. Klein's testimony.[9]

First it must be noted that substantial time was spent trying to determine the timing of the initial symptom of the KD. While both experts and the literature agree that the first symptom is a high-grade fever, Tr. at 59; 130, there is a discrepancy with the timing of onset of the fever between the contemporaneous medical records and the mother's affidavit. The mother states in her affidavit that the fever began "two hours after the immunizations." P Ex. 1 at 1. However, the contemporaneous histories given by the mother and father relate a slightly later onset period. See generally P Ex. 9; see also p. 4 infra. While it makes sense to accept the contemporaneous notations over the mother's recounting of facts years after the event, it is ultimately unnecessary to resolve the discrepancy. The critical fact is that by all accounts the onset of the KD was within 24 hours. See P Ex. 25 at 1; see also Tr. at 145, 149. Dr. Klein testified convincingly that such a relatively brief period is biologically implausible.

Dr. Klein was questioned ad nauseam on the issue of how fast of an onset would be biologically too fast, or put another way, what is the expected time frame for an autoimmune reaction. Based upon the mother's affidavit, Dr. Klein saw the two-hour onset period simply biologically implausible. Tr. at 126. The only explanation for such a quick reaction would be an anaphylactic reaction to the vaccine, and he and Dr. Byers agree that no such reaction occurred. See Id. at 127; see also P Ex. 35 at 1. While emphasizing that we are "hypothesizing" that an immune-complex reaction occurred, Dr. Klein stated that the expected time frame for the onset of symptoms would be days. Tr. at 129, 131. However, when pressed, he stated that "a day would be pushing it but still within the realm of conceivable phenomena." Id. at 130. However, Dr. Klein stated repeatedly that the expected time frame would be a week to ten days. Id. Complicating these biologic estimates further is the fact that Jordan was approximately two months old at the time of her immunizations. Dr. Klein explained that a two-month old has an "immature" immune system, and is relying on the protective antibodies of the mother. Id. at 132. The child does not begin developing immune capabilities until four to six months of age. Id. Accordingly, the child is unable to "mount a vigorous immune response. Dr. Klein explained that is why we give multiple vaccines to children. For example where you would give an adult one dose of pneumococcal vaccine to an adult, you would have to give four doses to an infant for adequate protection. Id. at 133. As it applies to KD, Dr. Klein postulated that the less mature response from an infant explains "why we see very few cases [of KD] the first few months of life." Id. at 134.

Dr. Byers did not address with specificity Jordan's early onset of the symptoms. She agreed that the onset was "about 24 hours after the immunizations." P Ex. 25 at 2. In her report, Dr. Byers wrote that the rash was the "initial presentation. Although a rash can be caused by both T cells and antibodies, the fact that it appeared within a day of vaccination is consistent with an antibody mediated mechanism of action, and since the child had previously been vaccinated only

[9] Petitioner did submit one case report that is arguably supportive of her case. P Ex. 32. That report is discussed infra at pp. 13-14.

with Hepatitis B, this is the likely culprit." Id. Very confusingly, Dr. Byers testified, consistent with the literature and Dr. Klein that the **fever**, not the rash, was the initial symptom of the KD. Tr. at 59, 67, 98. Further complicating her testimony, although she testified to antigen-antibody complexes which "could" form and result in vasculitis, she also testified to "superantigens" as a possible cause. The undersigned quizzed Dr. Byers at length on the issue of timing, asking whether an autoimmune reaction requires a minimal time for manifestation. Tr. at 98. It is quite frankly difficult to follow Dr. Byers' responses in the context of her entire testimony. The primary problem is that she testifies theoretically, never applying her theories to the facts and circumstances of a given case. See Rego v. Sec'y of HHS, No. 04-1734, Slip op. at 14 (Fed. Cl. Spec. Mstr. January 30, 2008). Thus, while she posited in her report the antigen-antibody complex as the most likely culprit, she never eliminates or explains the interrelationship of the other theoretical possibility of the superantigen. Thus, in construing the responses to timing, you are uncertain as to which mechanism she is speaking of, or whether it makes a difference. See Tr. at 97 - 101. The undersigned thus inquired of any support for a shortened time period for reaction, noting the importance in this case, by asking:

> The Court: Nowhere in any of the articles that were submitted here do you see a shortened timeframe. . . . They talk about the fever, and then they talk about the rash three to five days afterward. It's not qualified in any sense to depend upon if this an reintroduction of an infection or reexposure to an infection or vaccine or anything else.
>
> The Witness: I think I would have to say that the appearance of autoimmune diseases following various inciting factors is so variable that you really can't make that statement. I can make very clear a very strong statement that T cells and antibodies are seen quite a bit more rapidly after the second injection than after the first.
>
> • • •
>
> What I'm saying is that after the first injection of a vaccine, you're going to start seeing antibodies and T cells say within **two weeks**. After the second injection, you're going to start seeing them after like about **four days**.

Id. at 100-01 (emphasis added).

This statement would appear, alone and on its face, to defeat petitioner's claim since by any statement of facts the onset of Jordan's KD was within 24 hours. But Dr. Byers continued to confuse by responding again to a question of timing by saying:

> because I have a second mechanism of action, and it's because I really relied on that [Miron, P Ex. 32] paper where it was a mirror image of this one.

Id. The undersigned does not know how to interpret the first part of Dr. Byers' response regarding the second mechanism, because the timing questions the undersigned asked clearly addressed both theories and Dr. Byers was responding to both theories. See Tr. at 99. However, the case report,

the paper by Miron, is very meaningful since there are obvious parallels to the case at hand.

The above-aforementioned case report Dr. Byers referenced involved KD in an infant following HepB vaccine. The report discussed a previously healthy 35-day old Arab Muslim male in Northern Israel who developed a fever one day after the child's second dose of vaccination. P Ex. 32 at 1. The case report acknowledged that KD in infancy is rare. Id. at 2. Additionally, the case report stated that "Hepatitis B vaccine has been administered worldwide to millions of patients and fewer than 20 cases of vasculitis with a possible association with the vaccine have been reported. All patients were 16 or older." Id. The time-frame from when the infant in Israel received the second dose of vaccine and when the infant initially presented with symptoms of KD was shorter in the case report, 1 day, than in the cases reported with adults, 2 to 50 days with a median of 13 days for development of vasculitis. Id. The authors speculated to immune complex formation and superantigens as the cause, but could find no evidence of either. The case report noted the possibility that the hepatitis B surface antigen acted as a superantigen, while recognizing that this possible role of the hepatitis B surface antigen acting as a superantigen "has not yet been investigated." Id. at 3. This supports Dr. Klein's testimony that Dr. Byers' theory of the HepB vaccine serving as a superantigen is merely a hypothetical. Tr. at 167. The report continues, "Although it is impossible to determine a causative effect on an individual case report– and perhaps the association in this infant is coincidental– this case should be reported." P Ex. 32 at 3. The case report does not draw the conclusion that HepB vaccine caused KD in an infant one day after vaccination, but concludes that the strong temporal relationship to the vaccine and the rare development of KD in a 35 day old baby "should alert us to the possibility that the development of KD may be a rare side effect of hepatitis B vaccine." Id.[10] The experts could find no further case reports discussing HepB vaccinations and KD, or any studies on the issue. Tr. at 49, 172.

When you evaluate the totality of the evidence, it is clear that petitioner's medical theory simply is not reliable. It is well known in vaccine cases that autoimmune responses require a minimal time period for the body to mount such a response. See Tr. at 97-101; 127-28. It is also accepted that the period of time for the body's immune response will be shortened following a second vaccination, an anamnestic response. See Tr. at 101. In this case, we know that Jordan's fever, which is the accepted first symptom of her KD, occurred in less than 24 hours. In an effort to mine the earliest biologically plausible period of time for an autoimmune reaction; Dr. Klein was peppered with questions. Finally, he very reluctantly stated that if the onset, the fever, was at a day, Dr. Klein stated that it "would be pushing it but still within the realm of conceivable phenomena." Tr. at 130**.** He later stated that as you push that time frame further out "then the biologic plausibility becomes more evident." Id. at 178. Dr. Byers presented no convincing testimony to rebut Dr. Klein's statements, and the reams of literature were not discordant. See P Ex. 31 (two case reports of vasculitis occurring 10 and 30 days following the HepB vaccine); see also P Ex. 36 (two cases of immune-mediated PAN following the HepB vaccination occurring two weeks after the first dose and two days following the fifth dose). In fact, Dr. Byers'

[10]Dr. Byers agreed with the undersigned's observation that "that's why they do case reports, to bring it to the attention of the general public." Tr. at 93.

testimony, as best it can be interpreted, indicates that four days is the minimum time period following the second immunization. Tr. at 101. The only arguably supportive piece of evidence is the one case report. P Ex. 32.[11] The undersigned is unwilling and unable to find that one case report sufficiently probative to begin the evidentiary climb to a preponderance. Based upon the totality of the evidence on the issue of appropriate time frame and reliable medical theory, the undersigned finds that petitioner has failed to prove by a preponderance of the evidence that the vaccine could cause KD in less than 24 hours following the HepB immunization. Accordingly, the undersigned is unable to conclude that the vaccine is the "but for" cause of and substantial factor in Jordan's KD in the absence of preponderant evidence that the autoimmune reaction Dr. Byers supports can occur within less that a 24 hour period. Pafford, 451 F.3d at 1359.

Petitioner argues in closing that since we know Jordan has KD and given Dr. Klein's argument that the first symptom of KD is a fever, but that the fever occurring less that 24 hours following the immunization is too soon to be medically plausible, there must be a second fever -- where is the second fever? Transcript of October 22, 2007, Closing Argument at 9. The simple answer is that Dr. Klein never contended that there was a second fever; he merely testified that the vaccination could not be the cause of this initial symptom of KD because it occurred within a biologically unacceptable period of time. Based upon the Record in this case, the undersigned agrees. It is again emphasized that the cause of KD is unknown. The supposition of petitioner's argument is that the vaccine is the only apparent event occurring close in time to the onset of Jordan's KD and thus must be the cause. See Tr. at 91. This is not only legally incorrect, see Grant, 956 F.2d at 1148 (temporal relationship alone does not meet petitioner's burden), but as persuasively shown by Dr. Klein, it is faulty medical analysis as well.

There is a secondary reason, that is inextricably enmeshed in the first reason, for finding against petitioner. That is, it is illogical to conclude that the vaccine actually caused the KD in Jordan. The Federal Circuit made clear that the second part of its three-part test is not without meaning, stating that a petitioner could meet tests one and three (which were failed in this case) and still not satisfy prong two - demonstrating "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano III, 440 F.3d at 1327. An example of an illogical finding given by the Circuit was "where the probability of coincidence . . . prevents the claimant from proving that the vaccine caused the injury by preponderant evidence." Id. That is the situation in this case with regard to KD.

The etiology of KD is unknown. R Ex. C at 1; R Ex. E at 1; R Ex. F at 1; R Ex. H at 1; P Ex. 38 at 3; P Ex. 29 at 1; Tr. at 123. Dr. Byers postulates that KD is triggered by an inflammation, generally an infectious disease, "a wide range of infectious diseases." Tr. at 35. She cited as support the Scheinfeld article which says that "[i]ncreasing evidence supports an infectious etiology," P Ex. 38 at 3. While agreeing that a number of infectious agents have been

[11] Dr. Byers confirmed that she did a publication search prior to trial and did not find any further publications. Tr. at 49. Dr. Klein agreed. Id. at 172.

implicated, Tr. at 157, Dr. Klein maintained that "the Holy Grail is trying to find the etiology of Kawasaki disease." Tr. at 121. He stated that of the numerous viruses, "[n]one have been found associated consistently with" KD. Id. at 123; see R Ex. C at 3 (attempts to incriminate an infectious agent, however, have failed); R Ex. E at 2 ("During the past 30 years, identifying a definitive infectious agent that causes KD has not been possible."); see also R Ex. F at 9; but see R Ex. G at 1 ("the cause of the illness is unknown, although it is highly likely to be the result of infection with an unknown microbe."). Thus, without benefit of any reliable support for her premise that KD is triggered by inflammation caused by infection, Dr. Byers leaps to implicating the immunization as another potential cause. See Tr. at 35. To support this leap of medical logic, Dr. Byers relies upon several additional unsupported medical "facts", that is that KD is interchangeable with vasculitis, PAN and IPAN. While there is some support for KD and IPAN being "indistinguishable", see R Ex C at 2141; P Ex 33 at 2, there is no persuasive support for PAN and IPAN being interchangeable. See Tr. at 120 (Dr. Klein notes that PAN involves adults that "clearly is not the phenomena" that is involved in the childhood diseases of IPAN and KD); see also Tr. at 37 (Dr. Byers testified that the etiology of PAN and IPAN is "**probably** the same.") (emphasis added). Thus, Dr. Byers' heavy reliance on PAN literature to support this infant disease, KD, is unfounded. Even if one were to accept that faulty reasoning, the mounds of evidence regarding the unknowns of KD, despite the heavy efforts to understand the disease, coupled with the absence of positive evidence implicating the immunization, save the one case report, militate in favor of finding that the vaccines' role was coincidental, and thus it would be illogical to find a logical sequence of cause and effect." Capizzano III, 440 F.3d at 1327.

As Dr. Klein contended, it is implausible that the vaccine was the cause of Jordan's KD since "[m]illions of infants in the US have received the hepatitis B vaccine without KD identified as an adverse event." R Ex. D; see also Tr. at 181. As Dr. Klein explained:

> the vaccine we're using currently has actually been used in infants in the United States for about 10 years. It's estimated that by 2003, more than 40 million doses had been distributed to infants and children. It's estimated worldwide that a billion doses have been distributed. So there are going to be events temporally associated with this vaccine or other vaccines that would be linked to an event that occurred. So I think one has to be very careful. It's possible that a case will elicit a clue that one would like to follow up on, test whether the hypothesis that the vaccine is associated with Kawasaki would be supported. Now what would happen if in fact the vaccine in these 40 million children was associated with Kawasaki? And even if it were a very small incident of them, let's say it's one in 50,000 or one in 100,000, there have been 40 million doses administered. I would think that this type of case would come up at some intervals to elicit the interest of physicians.

Tr. at 139. Dr. Klein cites to Plotkin and Orenstein's Vaccines, for the statistical information that 40 million doses of hepatitis B vaccine were given to children in the United States in the past

seven years. R Ex. K.[12] Dr. Klein stated further that the notion of hepatitis B vaccine causing KD is "not only unproven and untested, but it's been unrecognized by people who spend their life thinking about KD." Tr. at 181. He elaborated "So for us to be in this courtroom and say we found the link, it's associated with hepatitis B vaccine, is implausible by itself." Id. There is no doubt that Kawasaki disease is a rare event. See Tr. at 157 (Dr. Klein has seen 12 patients in 30 years of practice, calling it an "uncommon" event). However, since its identification in 1974 there have been "almost 3000 articles" related to KD. R Ex. E at 1. As Dr. Klein explained the efforts to uncover the cause of KD:

> Well, the Holy Grail is trying to find the etiology of KD, and there are about half a dozen groups in the United States and Hawaii and Japan who have been knocking themselves out for decades trying to find the etiology. And sometimes they think they've found it, and then it's not corroborated in subsequent studies so that if they would find any link to something that might be fruitful they'd grab onto it and run with it. Whoever finds the etiology of KD is going to get prizes, fame, and these groups are in a race to use any clue that they could find to identify the etiology.

Tr. at 122. Yet despite the extensive efforts, the cause of KD remains unknown. Amongst all of this research, the only reference to the HepB vaccine being associated, not caused by but associated with, is the one case report. P Ex. 32. Again, Dr. Byers confirmed that a further search turned up no other articles. Tr. at 45, 49. It is worth noting that none of Jordan's doctors diagnosed the immunizations as the cause of Jordan's KD. See P Ex. 9 at 35, 37, 40-41, and 48. Petitioners are not required legally to produce objective confirmation of their theory of causation, Althen at 1279, nor must they identify a biological mechanism causing the injury, Knudsen, 35 F.3d at 548-49, however, petitioners must show in meeting the three prongs of Althen that "cumulatively . . . the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." Pafford, 451 F.3d at 1355. Given the extensive efforts devoted to uncovering the cause of KD, the billion doses of HepB vaccine distributed world-wide, except for the one case report, P Ex. 32, the lack of reported associated incidences of KD and HepB or any vaccine, the undersigned finds that petitioner failed to show that the vaccine was "logically" the cause of KD since the "probability of coincidence . . . prevents the claimant from proving that the vaccine caused the injury by preponderant evidence." Capizzano III, 440 F.3d at 1327.

Lastly, in deciding this case, the undersigned found Dr. Klein to be the vastly superior expert witness. His experience with Kawasaki disease, his extensive clinical practice and his testimony was far more persuasive and credible than that of Dr. Byers. Dr. Byers has run into criticism before, by this Special Master and by others. See Rego v. Sec'y of HHS, No. 04-1734, Slip op. at 14 (Fed. Cl. Spec. Mstr. Jan. 30, 2008) (Special Master found Dr. Byers' testimony "confusing, speculative, and frankly suspect" as it was not supported by the record or other

[12] Dr. Byers provided no rebuttal, but did state without citation or quantification that "we have not been vaccinating infants with hepatitis B for very long." Tr. at 45.

reliable sources.); Lawson v. HHS, No. 90-2455V, 2000 WL 246234 at *8 (Fed. Cl. Spec. Mstr. Feb. 14, 2000)("Dr. Byers created a theory and then tailored the facts to suit it."); see also Walther v. HHS, No. 00-426V, Slip op. at 4-5 (Fed. Cl. Spec. Mstr July 29, 2005)(Special Master criticized Dr. Byers' role as an expert witness), aff'd, 69 Fed.Cl. 123 (2005), rev'd on other grounds and remanded, 485 F.3d 1146 (Fed.Cir. 2007). Besides the problem with Dr. Byers' lack of clinical practice and extensive time, 50%, spent with litigation, see Simon v. Sec'y of HHS, No. 05-941V at 4-5, 2008 WL 623833 (Fed. Cl. Spec. Mstr. Feb. 21, 2008) (The undersigned found based on Dr. Loube's testimony that an expert should have "significant clinical experience" and should not "derive a significant portion of their income from testifying."), her testimony continuously raises questions of reliability and thus credibility. In short, Dr. Byers makes unsupported conclusory statements, and then working from those statements as if they are foundational facts issues opinions. However, when the bases for her opinions are parsed, what you find is one questionable supposition heaped upon another. The undersigned does not believe it is purposeful, but Dr. Byers, if she is going to continue as a viable witness, must improve greatly on substantiation of her medical theories and her understanding of the facts of a given case as she applies those medical theories in rendering her opinions. The undersigned will give a few examples of the questionable testimony that undercuts her credibility.

The most obvious example was the statement in her report that the first symptom of the KD was the rash. P Ex. 25 at 3. Her testimony was subsequently premised on the fever being the first symptom. See Tr. at 59, 67. The fever/rash issue was also the subject of extremely confusing and shifting testimony. See Tr. at 61-68. The undersigned saw the testimony consistent with my colleague's observation that "Dr. Byers created a theory and then tailored the facts to suit it." Lawson at *8. Also, Dr. Byers continuously makes qualified statements about medical propositions in building her foundation for causation. Thus, one theory of causation in this case was the vaccine being "found by some groups to serve as a superantigen." Tr. at 34. Beyond the question of how reliable is information from "some groups," Dr. Byers cites as support an article that merely states "whether the inflammatory response results from a conventional antigen or a superantigen continues to be debated." Tr. at 35 (referencing P Ex. 38). Not only does the article not support her proposition, it points out that the concept is being debated. It is this use of questionable statements and support, or in this instance no support at all, that leaves the decision-maker with no confidence in the statements from Dr. Byers. You simply do not know which statements are accurate and supportable and which ones are theoretical or still being studied. Unfortunately, Dr. Byers seems to treat all statements and theories alike and leaves the parties and decision-maker with the task of determining their validity. That is not the appropriate role of an expert.

However, the most egregious example of questionable testimony is the very loose use of medical terminology, again without support. Thus, Dr. Byers testified that the terms KD, PAN, IPAN and vasculitis can be used interchangeably. Beyond my experience in deciding vaccine cases over the 20 years with the medical profession using terms with great precision, not interchangeably, the medical literature submitted in this case does not support Dr. Byers. Of note, Dr. Klein took strong exception to Dr. Byers' contention. Tr. at 120-21. Dr. Byers relied upon P Ex. 33 for support of using terms interchangeably. In fact, Dr. Byers relied upon one sentence in

the article-- "Clinically, IPAN is often part of the spectrum of Kawasaki disease." -- to:

> extrapolate the case reports of hepatitis B virus and hepatitis B vaccination in patients, adult patients, with polyarteritis nodosa to extrapolate them to Kawasaki disease.

Tr. at 93-4. This is an extraordinary statement, both in its breadth and in its lack of foundational support. However, some of Dr. Byers' thinking can be gleaned from earlier testimony about this article. In this article, at P Ex. 33, which is an article about IPAN, the authors note that in 1970, Gocke, et al. demonstrated a link between hepatitis B surface antigen to the etiology of PAN. P Ex. 33 at unnumbered 5. Dr. Byers testified that Gocke, et al. were the "first ones to identify the etiology of hepatitis B itself as a cause of Kawasaki disease." Tr. at 40. However, the article does not say Kawasaki disease; it is Dr. Byers who inserts Kawasaki disease where the article discusses PAN. Later, Dr. Byers makes the next leap in her causation chain by inserting IPAN for PAN. Tr. at 93. Thus, while the article notes that Gocke, et al. demonstrated a link between hepatitis B surface antigen and PAN, Dr. Byers reads this to mean:

> –hepatitis B surface antigen causes PAN thus,
>
> –hepatitis B surface antigen causes IPAN and thus,
>
> –hepatitis B surface antigen causes Kawasaki disease.

See Tr. at 93. This syllogism is not supported by this article or any other literature provided in this case. A quick look at the article shows that the authors distinguished PAN and IPAN in their discussion. Two paragraphs after discussing the hepatitis B surface antigen as a cause of PAN, the authors discuss IPAN, stating:

> The cause of IPAN is not known. Almost since Kawasaki first described acute febrile mucocutaneous lymph node syndrome (MCLNS) of childhood, investigators have attempted to link it with infectious agents or antigens....[H]owever, no explanation has stood the test of time.

P Ex 33 at unnumbered 5. Clearly, the authors were not using the terms PAN and IPAN interchangeably, and clearly the authors were not ascribing a causative agent for IPAN. Dr. Byers is alone in both regards.

Similar problems were seen with Dr. Byers' unsupported working premise that the HepB virus and the HepB vaccine should be treated the same for causation purposes. Such an important ingredient to Dr. Byers' opinion cries out for support, but no reliable support is proffered. Dr. Byers testified that you look to the wild type virus in trying to uncover what the vaccine might cause, Tr. at 38, but as Dr. Klein testified the recombinant HepB vaccine is made of bits of DNA, it is not an attenuated virus vaccine like the measles, mumps, rubella vaccines. Tr. at 125; see also Stanley A. Plotkin, M.D. & Walter A. Orenstein, M.D., Vaccines 167-68 (3rd ed. 1999). Lastly, in explaining why there are not many articles describing KD, Dr. Byers states that "we

have not been vaccinating infants with hepatitis B for very long." Tr. at 45. However, as pointed out by Dr. Klein and later documented, there have been over 40 million doses of HepB vaccine in the United States and over one billion worldwide. See Tr. at 172; R Ex. K. In summary, Dr. Byers is not credible when she continuously makes general and questionable statements and then builds a theory of causation upon those statements. That simply is not reliable testimony.

In summary, the undersigned finds the timing of onset of KD, as contained in the facts of this case, was not biologically plausible. Thus, petitioner failed to prove by preponderant evidence a reliable medical theory or a proximate temporal relationship. Additionally, the undersigned finds that petitioner failed to establish a logical sequence of cause and effect since the weight of the evidence showed any relationship between Jordan's KD and her vaccines to be "coincidental."

Accordingly, the undersigned finds that petitioner has not established by a preponderance of the evidence that Jordan Shepperson's November 14, 2002 vaccinations were the legal cause of Jordan's KD. Petitioner's claim is denied. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

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Gary J. Golkiewicz
Chief Special Master